REMARKS

The withdrawal of the former rejections of claims 1-3,7-17, 19-26 and 33 under 35 U.S.C.§102(b) has been noted.

Claims 1,3, 7-12, 15-17,21-26 and 33 have now been rejected under 35 U.S.C.§103(a) as being unpatentable over Langauer in view of Conte.

Reconsideration is requested.

A minor amendment has been made to claim 1 to improve the syntax of the claim language. No new matter has been introduced. In the Office Action, Langauer was applied as teaching a tablet having a break or score assuring accurate and easy breakage into predetermined portions. The Examiner acknowledged that Langauer did not teach a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of a drug. The Conte patent was applied as disclosing a multilayer tablet where the first layer contains one or more drugs with an immediate or a controlled release formulation. The second layer contains a drug with a slow release formulation and a third layer which has a low permeability barrier coating. The Examiner concluded that it would be obvious to one of ordinary skill in the art to make a tablet where one side of the tablet had a score as taught by Langauer and to combine that tablet with the tablet disclosed by Conte which had a barrier (non-drug) layer that can be placed as a contiguous layer or as a layer between two active containing segments.

The claims point out a tablet having a first segment where one face is contiguous with substantially identical first and second unitary segments that contain a drug or drugs where said first segment contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug.

Langauer is a single layer homogeneous tablet which is scored but has no second layer. As a primary reference, it

does not teach the concept of the invention which requires a two layer tablet

The Conte patent points out that the third layer, is a low-permeability barrier coating said second layer. "This layer serves the purpose of limiting the drug release surface of the adjacent layer (col. 3, lines 40-41)."

Since the barrier layer is present for the purpose of limiting the rate of drug release from the tablet, one skilled in the art would not break the tablet through that layer and affect the surface area of the active ingredient layers that are contacted by gastric fluids. It is well known that controlled release pharmaceutical tablets are not to be broken, split or crushed because this can affect the release rate of the tablets and may cause dose dumping by changing the surface area of the active ingredients that is exposed to the action of gastric fluids. For example, the attached copy of the first page of an article from Drugs.com, mentions that as to Oxy-Contin sustained release tablets, one should not "break, crush, chew, dissolve, or split" those tablets as "doing so may cause the release of too much medicine into the bloodstream, which could be fatal."

Col. 5, lines 51-53 of the Conte patent points out that the function of the barrier layer is to avoid dose dumping and this teaching would direct a skilled artisan away from breaking the barrier layer taught by Conte.

Attached hereto is an article by Conte et al., which explains that the barrier layer in the Geomatrix tablets that are disclosed in the cited patent to Conte et al., are designed to swell simultaneously with the core in order to cover the base of the core until the end of the dissolution process. Breaking the tablet would prevent the tablet from operating as it was designed because it would change the ratio of coated-uncoated surface and increase the surface area of the active layers that are exposed to gastric juices. This would cause the rate of release to be accelerated. The attached article about "Split Paxil CR" tablets, discloses

that the these tablets are controlled release Geomatrix tablets and that "splitting Paxil CR tablets increases the surface area that is available to be dissolved" and "will most likely make them like regular Paxil tablet". Thus it is not obvious to score for breaking and/or break the controlled release tablets disclosed by Conte.

The Conte patent requires that the first and second contiguous segments must both contain drugs and that the third non-contiguous segment be the segment that has no drug. This is because in the Conte tablet, the third non-contiguous layer is a barrier layer which coats one base of the compressed tablet or the side surface and one base of the tablet(Conte, col. 5, lines 45-47. The barrier cannot function as a barrier for controlled release purposes if it is scored in the manner specified in the amended claims of the present application. In addition, if the score is placed in layer 1 of the Conte tablet, the controlled release layer will break and the controlled release barrier layer 3 will also break and adversely affect the controlled release properties of the tablet. The tablet defined by the claims of the present application can only be made by proceeding contrary to the Conte disclosure which is a hallmark of non-obviousness. It is not obvious to make a tablet that has a structure which can only be made by ignoring the teachings of the prior art.

Even when Conte is combined with Langauer, there is no reason to modify Conte and have only one active segment contiguous with an inactive segment.

Claim 8 points out a tablet in which the first segment contains no more than 10% of the concentration of drug or drugs present in the first unitary segment and said second unitary segment. This is not suggested by either the Langauer or Conte patents when considered alone or in combination.

Claim 9 points out a tablet in which the first segment contains no more than a 2% concentration of the drug

that is present in the first unitary segment and said second unitary segment. This is not suggested by either the Langauer or Conte patents when considered alone or in combination.

Claim 10 points out a tablet as defined in which the first segment is derived from a granulation that does not contain a drug. This is not suggested by either the Langauer or Conte patents when considered alone or in combination.

Claim 15 points out an embodiment having a vertical score aligned with the center of the space between said first unitary segment and said second unitary segment. This structure is not made obvious by the Langauer or Conte patents.

In paragraph 9 of the Office Action, claims 17-18 were rejected under 35 U.S.C.§103(a) over Langauer and Conte in view of Addicks et al. (Addicks).

Reconsideration is requested.

The Langauer patent has been distinguished from amended claim 1 above and nothing in Conte or Addicks discloses the invention as defined by claims 17 and 18. Claims 17 and 18 depend on claim 1 which requires that a specific first segment be contiguous with the defined first and second unitary segments of the tablet. Addicks is only concerned with a two layer tablet that has no score and has no "layer where said first segment contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug" as pointed out in claim 1. For these reasons, it is requested that this ground of rejection be withdrawn.

In paragraph 9 of the Office Action, Claims 17 and 19 were rejected under 35 U.S.C.§ 103(a) as being unpatentable over Langauer in view of Conte and further in view of Eberlin et al. (Eberlin).

Reconsideration is requested.

The Langauer and the Conte patents have been distinguished from amended claim 1 above and nothing in Eberlin discloses the invention as defined by claims 17 and

19, which depend from amended claim 1. Claim 1 requires a specific first segment to be contiguous with the defined second segment of the tablet. Eberlin is concerned with a tablet that comprises digoxin and provides no information that makes the claimed tablet obvious. For these reasons, it is requested that this ground of rejection be withdrawn.

In paragraph 11 of the Office Action, Claims 17 and 20 were rejected under 35 U.S.C.§ 103(a) as being unpatentable over Languer and Conte in view of Franz et al. (Franz).

Reconsideration is requested.

The Langauer and Conte patents have been distinguished from amended claim 1 above and nothing in Franz discloses the invention as defined by amended claim 1 which requires a specific first segment to be contiguous with the defined second segment of the tablet. Claims 17 and 20 depend directly or indirectly from claim 1 and claims 17 and 18 are patentable for the reasons set forth above. Franz is only concerned with a tablet that comprises levothyroxine sodium. For these reasons, it is requested that this ground of rejection be withdrawn.

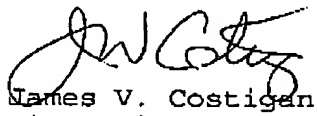
Claims 1-3, 7-12, 15-26 and 33 were provisionally rejected for double patenting over Serial No. 11/441,455 and these claims have also been rejected over U.S. 7,329,418 and U.S. 7,318,935 for double patenting.

Terminal Disclaimers for the provisional rejection over Serial No. 11/441,455 and U.S.7,318,935 and U.S. 7,329,418 are attached to this Amendment.

The applicants have disclosed a novel and unobvious invention and patent protection should be allowed.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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